

**Notice of Allowability****Application No.**

10/044,564

**Examiner**

Robert A. Wax

**Applicant(s)**

RASTELLI ET AL.

**Art Unit**

1653

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the election/amendment filed August 30, 2004.
2. ☒ The allowed claim(s) is/are 20-22,24,25,27-29,34-36,54,57,61 and 62.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Robert A. Wax  
Primary Examiner  
Art Unit: 1653

**DETAILED ACTION**

***Election/Restriction***

1. Applicant's election with traverse of Group V in the reply filed on August 30, 2004 is acknowledged. The traversal is on the ground(s) that by detecting the nucleic acid of Group V the method of detecting becomes part of Group V and that a search of the sequence would also identify methods of determining the presence or amount of the nucleic acids and, therefore, no serious burden exists. This is not found persuasive because the premise is incorrect. Detecting the nucleic acid is a method of use of the nucleic acid, not the nucleic acid itself and the practice of the method does not transform the method into the product. The search is not coextensive, since more searching needs to be done to identify methods of use of the product, not all references that are found during a search of the product will also teach the method.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 20-22, 24, 25, 27-29, 54 and 57 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 34-36, 61 and 62, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 34-36, 61 and 62 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the Office action mailed on June 28, 2004, with respect to Groups V and VII is hereby withdrawn.

***Information Disclosure Statement***

3. The information disclosure statements filed April 30, 2002, December 6, 2002 and September 2, 2004 have been considered. Please see the attached initialed PTO-1449s.

***Inventorship***

4. In view of the papers filed August 30, 2004, under 37 CFR 1.48(b), the inventorship in this nonprovisional application has been changed by the deletion of Peter D. Mezes, Stacie Casman, Ferenc Boldog, Richard A. Shimkets, Linda Gorman, Andrew J. Eisen, Steven K. Spaderna, Corine A.M. Vernet, Constance Berghs, Kimberly A. Spytek, Vincent A. DiPippo, Bryan D. Zerhusen, John A. Peyman, Karen Ellerman, David J. Stone, William M. Grosse, John P. Alsobrook II, Denise M. Lepley, Daniel K. Rieger, Catherine E. Burgess and Shlomit R. Edinger.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

### **REASONS FOR ALLOWANCE**

5. The following is an examiner's statement of reasons for allowance:

The instant invention is directed to a nucleic acid encoding a polypeptide having SEQ ID NO: 38, particularly SEQ ID NO: 37, vectors, host cells and pharmaceutical compositions containing the nucleic acid and methods for determining the presence or amount of the nucleic acid and a method for determining the presence of or predisposition to a disease associated with altered levels of the nucleic acid molecule.

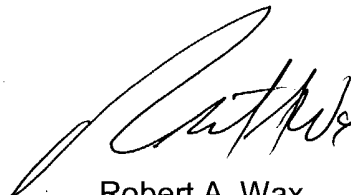
A search for the claimed nucleic acids showed that SEQ ID NOs: 37 and 38 are novel. The specification characterizes SEQ ID NOs: 37 and 38 as encoding or being NOV7, which is similar to prominin. Carbeil et al. (Reference C10) support this contention and provide evidence of utility of the claimed invention. For these reasons, the instant claims are deemed patentable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'R. Wax', is positioned above the printed name and title.

Robert A. Wax  
Primary Examiner  
Art Unit 1653

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